REMARKS

Claims 1-5, 9, 23 and 27-37 are pending in this application. Entry of the remarks is respectfully requested.

I. Claim Rejection under 35 U.S.C. § 112, First Paragraph

Claim 37 stands rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. Specifically, the Examiner alleges that because the specification does not recite a specific dose of "about 5 mg per day," the amendment to claim 37 reciting this dose constitutes new matter. (Office Action, page 3). Applicants respectfully disagree.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Manual of Patent Examining Procedure ("MPEP") § 2163. When new claims are added, there is no *in heac verba* requirement, as long as the newly added claim is supported in the specification through "express, implicit, or inherent disclosure." *Id.*

Claim 37, which was added in Applicant's previous response dated July 9, 2007, recites a specific dose of about 5 mg per day. The specification provides a dose range of about 5 to 25 mg per day at page 24, lines 24-25. The specification need not recite the specific dose of about 5 mg per day because one skilled in the art, reading the narrow range recited in the specification, would reasonably conclude that the inventor had possession of the claimed invention.

The Examiner cites *In re Smith* to support the argument that the dosage range of the specification does not support the specific dose of claim 37. 458 F.2d 1389 (C.C.P.A. 1972). In *Smith*, a subgenus or range of "at least 8 carbon atoms" was not found to be supported by an earlier genus reciting "at least 12 carbon atoms." *Id.* at 1396. The instant case is distinguishable from *Smith* because claim 37 recites a single species supported by a narrow range, not a sub-range or genus of an earlier disclosed broad genus. A limited number of species are possible from the 5 mg to 25 mg range of the instant specification, as compared to the infinite possible subgenuses available

in *Smith*.[1] The instant case is analogous to *Hunt v. Treppschuh*, in which the Court held that a claimed species was supported by the earlier disclosure's narrow genus. 523 F.2d 1386, 1388-89 (C.C.P.A. 1975). Because the prior disclosure's genus was small and well-defined, one skilled in the art could easily arrive at the later claimed species *Id.* The Court distinguished *Smith* because the disclosure relied upon for support in *Smith* "encompassed an infinite number of subgenera." *Id.* at 1389 n.8. Therefore, like *Hunt*, the single species dose of claim 37 is adequately supported by the small dose range of the instant specification. For these reasons, Applicants request that the rejection for lack of written description be withdrawn.

II. Claims Rejections under 35 U.S.C. § 103

A. Claims 1, 9, 27-30 and 33-34 are Patentable over Omoigui in view of Olmarker *et al.*

Claims 1, 9, 27-30 and 33-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Omoigui (U.S. 2004/0038874, "Omoigui") in view of Olmarker, *et al.* (WO 2002/080891, "Olmarker") (Office Action, page 5). Applicant respectfully disagrees.

In *KSR International Co. v. Teleflex Inc.*, the U.S. Supreme Court rejected the Federal Circuit's *rigid application* of the "teaching, suggestion, motivation" test ("the TSM test") in determining obviousness in the particular case in question. 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, 1395 (2007) (emphasis added). According to the Supreme Court, the correct analysis is set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). *Id.* However, the *KSR* decision indicated that while the TSM test is not the sole method for determining obviousness, it may still be used and in some cases is helpful. *Id.* at 1396. ("When it first established [the TSM test], the Court...captured a helpful insight."). Indeed, the guidelines for the examination of patents in the wake of the *KSR* decision make clear that an Examiner may still apply the TSM test, after resolution of the *Graham* analysis. *See* Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57528 (Oct. 10, 2007) ("USPTO Guidelines").

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[1] Applicant points out that dosages of at least 5 mg increments are most commonly used in the pharmaceutical arts, therefore, the practical number of species in a 5 mg to 25 mg dose range is actually five (5, 10, 15, 20 and 25 mg dosages).

The *Graham* factual inquiries are: (1) determine the scope and contents of the prior art; (2) ascertain the differences between the prior art and the claims at issue; (3) resolve the level of ordinary skill in the pertinent art; and (4) evaluate any evidence of secondary considerations. *KSR,* 82 U.S.P.Q.2d at 1395 (*citing Graham,* 383 U.S. at 15-17). Once the *Graham* factors have been addressed, the Examiner may apply the TSM test, asking whether (1) a teaching, suggestion or motivation exists in the prior art to combine the references cited, and (2) one skilled in the art would have a reasonable expectation of success. *See* USPTO Guidelines at 57534.

1. The *Graham* factual analysis.

The *Graham* factual inquiries begin with an analysis of the scope and content of the prior art, in view of the scope of the claimed invention. *See* USPTO Guidelines at 57527 (*citing Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)). The instant claims recite, *inter alia*, methods of treating a specific disease, complex regional pain syndrome, with a specific dose of a specific compound, 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione. The prior art cited by the Examiner consists of Omoigui and Olmarker. Omoigui teaches that pain of all kinds may be treated by mediating the inflammatory response with any of hundreds or thousands of drugs that may impact inflammation. Omoigui does not teach or suggest 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione. Olmarker teaches that TNF-α inhibitors may be used to treat low back pain. Olmarker does not disclose or suggest the use of the specific compound in specific amounts for treating complex regional pain syndrome as recited in the instant claims.

Regarding the differences between the prior art and the claims at issue, Applicant points out that the claimed invention is not described, taught or suggested by the references cited by the Examiner. The scope of the instant claims, which recite a specific compound, is in stark contrast with the breadth and general teachings of Omoigui and Olmarker, wherein hundreds if not thousands of compounds are described. The remarks below address these differences in detail, following the well-established case law concerning the obviousness of chemical compounds. *See Takeda Chemical Ind., Ltd. v. Alphapharm Pty., Ltd.*, 429 F.3d 1350 (Fed. Cir. 2007).[2]

[2] Applicant asserts that the first and second *Graham* factors are of greatest importance in this case, however, Applicant reserves the right to later present arguments regarding the level of ordinary skill in the art and evidence of secondary considerations.

2. The Examiner has failed to make a *prima facie* case of obviousness based on alleged structural similarity.

In the context of claims to chemical compounds and their biological properties, the Federal Circuit has recently applied the TSM test under 35 U.S.C. § 103. *See Takeda Chemical Ind., Ltd. v. Alphapharm Pty., Ltd.*, 429 F.3d 1350 (Fed. Cir. 2007). In *Takeda*, the Court held that the compounds at issue were not *prima facie* obvious over structurally similar "compound b" of the prior art because the prior art provided no motivation to modify compound b to arrive at the claimed compounds, and there was no reasonable expectation that the modification would provide the desired pharmacological properties. *Id.* at 1360. Indeed, the court noted that "we have cautioned 'that generalization should be avoided insofar as specific chemical structures are alleged to be prima facie obvious one from the other.'" *Id.* at 1361 (*quoting In re Grabiak*, 769 F.2d 729, 731 (Fed. Cir. 1985)). Thus, the current law of obviousness in cases concerning structurally similar compounds "requires a showing of 'adequate support in the prior art' for the change in structure." *Id.* at 1356 (*quoting In re Grabiak*, 769 F.2d at 729).

The instant claims are not obvious because the Examiner has not shown adequate support for the selection of the specific compound of the instant claims from the teachings of Omoigui and Olmarker. Omoigui teaches the treatment of pain of any type by mediating the inflammatory response with any of thousands or more drugs that may impact inflammation. This extremely broad teaching can hardly be said to focus on thalidomide analogs. But even if it did, Omoigui provides no teaching or suggestion of any particular thalidomide analogs, not to mention the specific compound of the instant claims. As was the case in *Takeda*, there is no showing of support for the change in structure from the compound of the prior art (in this case thalidomide), to the compound of the instant claims.

The Examiner alleges that, compared to thalidomide, 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione "only differs in the removal of one ketone and the addition of one amino group." (Office Action, page 7). Applicant respectfully points the Examiner to *Takeda*, in which the court found that a change from a methyl group at the 6-position of a compound to an ethyl group at the 5-position was not *prima facie* obvious. *Id.* at 1359. In stark contrast to the facts of *Takeda*, the structural changes required to make 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione from thalidomide require the complete removal of

one of four different carbonyl groups, and the addition of an amino group at one of four positions on the aromatic ring. The references cited by the Examiner provide no guidance for these changes, much less a reasonable expectation of success. Moreover, unlike the homologous substitution of methyl for ethyl in *Takeda*, any number of different substituents besides an amino group could have been selected to replace the hydrogen in thalidomide. As the Court held in *Takeda*, the prior art cited by the Examiner does not provide a "finite number of identified, predictable solutions," but a "broad selection of compounds any of which could have been selected as the lead compound for further investigation." *Id.* at 1359. *see also In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."). Therefore, in view of the current law of obviousness in cases of allegedly similar compounds, the Examiner has not provided adequate support in the prior art for the instant change in structure. *See Id.* at 1356. For these reasons alone, a *prima facie* case of obvious cannot be made.

3. One skilled in the art would have no reasonable expectation of success to arrive at the instant claims in view of the teachings of Olmarker and Omoigui.

The Examiner alleges that one skilled in the art would have a reasonable expectation of success because Olmarker "already discloses that the compound can be used to treat other TNF-α dependent pain syndromes such as lower back pain." (Office Action, page 5). Applicant disagrees.

To have a reasonable expectation of success, "one must be motivated to do more than merely 'vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave...no direction as to which of many possible choices is likely to be successful.'" *Medichem, S.A. v. Robaldo*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (*quoting In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). Furthermore, the courts have long recognized the unpredictability of biological properties of chemical compounds. *See In re Eli Lilly & Co.*, 902 F.2d. 943, 948 (Fed. Cir. 1990) ("we recognize and give weight to the unpredictability of biological properties..."); *see also Takeda*, 429 F.3d at 1361.

Olmarker merely discloses that TNF-α inhibitors may be used to treat low back pain. The specific compound of the instant claims is one of over eighty compounds and classes of compounds taught to be TNF-α inhibitors in Olmarker.

One skilled in the art would have no reasonable expectation that the specific compounds of the instant claims would be useful to treat a specific disease not taught in Olmarker at all.

Omoigui does not cure this defect. Omoigui teaches the treatment of pain of all kinds by mediating the inflammatory response with any drug that may impact inflammation. Omoigui provides no direction as to what particular drug should be used to treat each specific type of pain. Even assuming, *arguendo*, that one skilled in the art would be motivated to select 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione from Olmarker, there would be no reasonable expectation that the compound would successfully treat complex regional pain syndrome– one of the many type of pain related diseases or disorders mentioned in Omoigui.

Simply put, to arrive at the methods of the instant claims, one skilled in the art must "vary all parameters or try each of numerous possible choices" of Omoigui and Olmarker without "direction as to which of many possible choices is likely to be successful." *Medichem*, 437 F.3d at 1165. This is precisely what the courts have held not to be a reasonable expectation of success. *Id.*; *O'Farrell*, 853 F.2d at 903-04.

Because the Examiner has not demonstrated that one skilled in the art would have had a reasonable expectation of success in practicing the methods of the instant claims by combining the teachings of Omoigui and Olmarker, the Examiner has failed to state a *prima facie* case of obviousness. Therefore, the instant claims are not obvious over Omoigui in view of Olmarker.

4. Olmarker teaches away from the claimed dosage range.

Applicant reasserts that Olmarker teaches away from the claimed dosage range. Prior art is said to teach away from a claimed invention "[w]hen a piece of prior art 'suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant....'" *Medichem*, 437 F.3d at 1165 (*quoting In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)) (emphasis added); *See also KSR*, 127 S.Ct. at 1740 (*citing United States v. Adams*, 383 U.S. 39, 40 (1966)); MPEP § 2145 (citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983)). The Examiner alleges that one skilled in the art would "have naturally experimented with different higher and lower dosage levels," based on the dosage ranges taught by Olmarker. (Office Action, page 7). While it may be true that one skilled in the art would generally seek to vary dosage ranges to

optimize results, Applicant respectfully points out that one skilled in the art, reading Olmarker, would not be motivated to experiment in the low dosage range as instantly claimed. Olmarker teaches that a dosage of 200-800 mg is "more preferred," and a dosage of 400-600 mg is "most preferred." (page 11, line 30). If one skilled in the art was motivated to select the specific compound of the instant claims from Olmarker, they would certainly be motivated to use the preferred dosages taught therein, not the much lower dosage of the instant claims. Thus, the dosage range disclosed by Olmarker for the specific compound of the instant claims teaches away from the dosages of the instant claims.[3]

5. There are sufficient unexpected results to rebut even a *prima facie* case of obviousness.

Further, even assuming, *arguendo*, a *prima facie* case of obviousness is established by the cited references in combination, there is evidence of unexpected or superior results for the activity of the recited compound to rebut a *prima facie* case of obviousness. As the Examiner is well aware, such unexpected results can rebut even a *prima facie* case of obviousness. *In re May*, 574 F.2d 1082, 1094 (C.C.P.A. 1978); *see also In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); *Ortho-McNeil Pharmaceutical v. Mylan Laboratories*, 348 F. Supp. 2d 713, 755 (N.D. W. Va. 2004).

As discussed below, the claimed compound (3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione), lenalidomide or CC-5013, surprisingly showed significant efficacy and safety in treating complex regional pain syndrome in human patients. Therefore, the claimed method is a superior and unexpectedly better method of treating complex regional pain syndrome than conventional therapies.

A clinical *in vivo* study of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione was performed to evaluate the efficacy and safety of the claimed compound using adult humans with chronic, unilateral Type 1 complex regional pain syndrome. G. Irving *et al.*, "A multicenter, open-label study to evaluate the safety and efficacy of lenalidomide (CC-5013) in the treatment of type-1 Complex Regional Pain Syndrome (CPRS)." Conference in the Mechanisms and Treatment of

[3] Applicant points out that the dosages of new claim 35 (about 5 mg to 25 mg per day) and new claims 36 (about 10 mg per day) and 37 (about 5 mg per day) are certainly not taught or suggested by Olmarker.

Neuropathic Pain, November 4-6, 2004, Bermuda (copy enclosed). The results of the study showed that 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione unexpectedly provided significant reduction in pain in subjects nonresponsive to conventional therapy. Adverse events were mild and time-limited, indicating that the compound was surprisingly safe in human subjects.

In sum, the surprising efficacy and safety of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in treating complex regional pain syndrome is sufficient to rebut even a *prima facie* case of obviousness. In view of these unexpected results, the instant claims are not obvious. *See In re May*, 574 F.2d at 1094. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.

B. Claims 2-5 and 23 are Patentable over Omoigui in view of Olmarker and Merck.

Claims 2-5 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Omoigui in view of Olmarker, further in view of the Merck Manual of Diagnosis and Therapy, Seventeenth Edition ("Merck") (Office Action, page 8). The Examiner alleges that the instant claims are obvious because Omoigui teaches the use of thalidomide derivatives to treat complex regional pain syndrome, Olmarker discloses that 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione may be used to treat low back pain, and Merck discloses that complex regional pain syndrome may be treated with certain drugs, physical therapy and/or surgery. (Office Action, page 8). Applicant respectfully disagrees.

As discussed above, Omoigui in view of Olmarker does not teach or suggest each and every element of the instant claims. Neither Omoigui nor Olmarker discloses or suggests the specific compound in specific amounts as recited in instant claim 1, to treat complex regional pain syndrome. Merck does not cure this defect. Merck merely teaches that certain drugs, physical therapy and/or surgery may be used to treat complex regional pain syndrome. Merck does not disclose or suggest 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione, not to mention specific dosage ranges for treating complex regional pain syndrome. Merck does not even suggest any method of combination therapy as claimed. Therefore, the instant claims are not obvious over Omoigui in view of Olmarker, further in view of Merck.

C. Claims 31-32 are Patentable over Omoigui in view of Olmarker and Remington.

Claims 31 and 32 stand rejected under 35 U.S.C. § 103(a) as unpatentable under Omoigui in view of Olmarker, further in view of Remington, *et al.* ("Remington") (Office Action, page 9). The Examiner alleges that because Remington discloses that different enantiomers of the same compound may possess different pharmacological activities, one skilled in the art would be motivated to combine this knowledge with the teachings of Omoigui and Olmarker, discussed above, to practice the methods of claims 31 and 32. *Id.* Applicant respectfully disagrees.

As discussed above, Omoigui in view of Olmarker does not teach or suggest the use of the specific compound in specific amounts as recited in instant claim 1, to treat complex regional pain syndrome. Remington does not cure this defect. Remington does not disclose or suggest anything about 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione, not to mention specific dosage ranges for treating complex regional pain syndrome using this specific compound.

There is no *per se* rule that a stereoisomer is obvious in view of the disclosure of another stereoisomer in the prior art. *Ex Parte Bonfils*, 64 U.S.P.Q.2d 1456, 1461 (B.P.A.I. 2002)[4] (*citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995)). Indeed, the Federal Circuit and its predecessor have repeatedly stated that "generalization is to be avoided insofar as specific structures are alleged to be *prima facie* obvious one from the other." *In re Jones*, 958 F.2d 347, 350 (Fed. Cir. 1992) (*citing In re Grabiak*, 769 F.2d at 731); *see also Takeda*, 429 F.3d. at 1361 (also citing *Grabiak*); *In re Lancer*, 465 F.2d 896, 899 (C.C.P.A. 1972) ("Homology should not be automatically equated with *prima facie* obviousness....").[5]

The Examiner cites Remington for the general idea that "different enantiomers of the same compound may possess different biological and pharmacological activities." (Office Action, page 10) (emphasis added). Applicant points out that Remington merely provides a single example, epinephrine, to illustrate that different enantiomers may possess different biological and pharmacological properties. Remington does not teach that the biological or pharmacological activity of a specific

[4] Nonprecedential decision, copy enclosed.

[5] Furthermore, as the Court noted in *KSR*, obviousness is an objective, fact-specific inquiry. *See KSR*, 127 S.Ct. at 1734.

enantiomer is predictable from the racemate, nor does Remington provide any guidance regarding the compound of the instant claims. Indeed, whether a specific enantiomer has improved biologically activity or a more desirable pharmacological profile is recognized as unpredictable in the art. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d. 713, 754 (N.D. W. Va. 2004) (the prior art suggested unpredictability in the degree of activity exhibited by a specific enantiomer); *see also Forest Labs., Inc. v. Ivax Pharmaceuticals, Inc.*, 438 F. Supp. 2d 479, 493 (D. Del. 2006); *Bonfils*, 64 U.S.P.Q.2d at 1461. Therefore, Omoigui in view of Olmarker and Remington does not provide sufficient motivation to prepare a specific enantiomer of the compound of the instant claims because there is no predictability that either of the enantiomers will provide significantly improved biological or pharmacological properties. For these reasons, claims 31-32 are not *prima facie* obvious over Omoigui in view or Olmarker and Remington.

The Examiner further alleges that "testing two enantiomers for a known activity to determine which is the best drug candidate is a small and routine experimental burden well within the ordinary level of skill in the art." (Office Action, page 11). To the contrary, it is well known to those skilled in the chemical and pharmaceutical arts that the separation, preparation and testing of stereoisomers is not predictable, nor are these processes always a small or routine burden. *See* J. Darrow, "The Patentability of Enantiomers: Implications for the Pharmaceutical Industry," 2007 Stanford Tech. L. Rev. 2, ¶56 ("the process for making the racemate may not make obvious a process for resolving the racemate.") (copy enclosed). Thus, without specific guidance in the prior art, one skilled in the art would have no reasonable expectation of success in isolating or synthesizing a specific enantiomer of the compound of the instant claims. Remington, which provides no teaching of how to isolate or synthetically prepare the R or S isomer of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione, does not cure this defect. Therefore, claims 31-32 are not *prima facie* obvious over Omoigui in view of Olmarker and Remington.

III. Obviousness-Type Double Patenting Rejection

Claims 1, 6 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 8 of U.S. Patent No. 5,635,517 ("the '517 patent") in view of Omoigui. (Office Action, page 12). Applicant respectfully disagrees.

Obviousness-type double patenting is a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not "patentably distinct" from the claims of a first patent. *See In re Braat*, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991). In *General Foods Corp. v. Studiengesellschaft Kohle mbH*, the Federal Circuit further explained that in an obviousness-type double patenting rejection "it is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference." 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992). Applicant respectfully submits that the Patent Office is mistaken concerning what is claimed in the claims of the '517 patent, and by not considering what the claims of the '517 patent define, the Patent Office arrives at a legally improper double patenting rejection of the claims.

The instant claims are drawn to methods for treating a specific disease—complex regional pain syndrome—using a specific amount of a specific compound. The claims of the '517 patent merely recite methods of reducing undesirable levels of TNF-α in a mammal, without any reference to complex regional pain syndrome. The claims of the '517 patent provide no suggestion or motivation for one skilled in the art to select the specific compound of the instant claims to treat the specific disease of the instant claims.

The Examiner alleges that Omoigui "discloses that complex regional pain syndrome...is a specific pain disorder that can be treated by the disclosed method." (Office Action, page 14). While Omoigui does mention complex regional pain syndrome as one of many specific pain disorders, the Examiner has failed to demonstrate why one skilled in the art would select complex regional pain syndrome from the many diseases and disorders listed in Omoigui and apply that teaching to the claims of the '517 patent in order to arrive at the instant claims. Without demonstrating why one skilled in the art would be motivated to make this specific selection, the instant claims cannot be obvious over the claims of the '517 patent in view of Omoigui. *See KSR*, 82 U.S.P.Q.2d at 1395 (Examiner must "identify a reason that would have prompted a person of ordinary skill...to combine the elements in the way the claimed new invention does."). The claims of the '517 patent in view of

Omoigui do not teach or suggest a method of treating the specific disease of the instant claims, much less doing so with a specific amount of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione. For these reasons, the instant claims are patentably distinct from the claims of the '517 patent, and the double patenting rejection must be withdrawn.

Furthermore, the policy behind a double patenting rejection—the prevention of an unjustified extension of the term of a patent—does not support the Examiner's rejection in this case. *See In re Braat*, 19 U.S.P.Q.2d at 1291-92; *see also In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986) ("the basis for...obviousness-type double patenting rejections is timewise extension of the patent right"). Allowance of the instant claims, directed to the treatment of complex regional pain syndrome with a specific compound, would not result in the timewise extension of the term of the '517 patent. Therefore, Applicants respectfully request that the double patenting rejection be withdrawn.

CONCLUSION

In view of the foregoing, all the rejections of the claims should be withdrawn. Reconsideration, entry of the above remarks and allowance of the pending claims are respectfully requested. Should the Examiner not agree that all claims are allowable, a personal or telephonic interview is respectfully requested to discuss any remaining issues and to accelerate the allowance of the above-identified application.

Please apply fees for a Request for Continued Examination ($810.00), and any other charges, or any credits, to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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